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Re-evaluation Decision RVD2016-04

Imazamox

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Re-evaluation Decision

Imazamox is a selective post-emergence herbicide, used for the control of broadleaf and grassy weeds in crops with imidazlinone tolerance in the Prairie provinces, Peace River region of British Columbia and Eastern Canada. There are 15 products containing imazamox that are currently registered in Canada under the authority of the Pest Control Products Act, including 1 technical grade active ingredient and 11 commercial class end-use products and 3 manufacturing concentrates.

It is approved for use in several Clearfield crops, soybean peas, dry edible beans (tank mix only), fenugreek for seed and forage uses, seedling and established alfalfa grown for seed, and bird's foot trefoil for seed production.

After a re-evaluation of imazamox, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act*, is granting continued registration of products containing imazamox for sale and use in Canada. An evaluation of available scientific information found that products containing imazamox do not present unacceptable risks to human health or the environment when used according to the conditions of registration, which include amended label directions. Label amendments are required for all end-use products as summarized below and listed in Appendix II. No additional data are requested at this time.

Human Health

- Restricted-entry interval.
- Precautionary label statement to minimize bystander exposure from spray drift.

Environment

- Buffer zone and label statements to protect non-target terrestrial plants.
- Environmental hazard label statements

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2012-02, *Re-evaluation Program Cyclical Re-evaluation*, presents the details of the cyclical re-evaluation approach, which is in line with the requirements of the *Pest Control Products Act*.

This re-evaluation decision[1] was proposed in the consultation document, Proposed Re-evaluation Decision PRVD2015-04, *Imazamox*. One comment was received during the consultation process. Appendix I summarizes the comment received during the consultation process and the PMRA's response to this comment. This decision is consistent with the proposed re-evaluation decision stated in PRVD2015-04. A reference list for all data used as the basis for the re-evaluation decision is also included in PRVD2015-04.

[1] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

To comply with this decision, the required mitigation measures must be implemented on all products labels sold by registrants no later than 24 months after the publication date of this decision document.

Other Information

Any person may file a notice of objection[2] regarding this decision on imazamox within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

[2] As per subsection 35(1) of the *Pest Control Products Act*

Appendix I Comments and Responses

In response to the consultation document PRVD2015-04, *Imazamox,* comments related to the health assessment were received from the registrant.

Comment- No Observed Effect Level (NOEL)

The registrant requested clarification as to the source of the cited NOEL of 870 mg/kg bw/day. In the two year rat feeding study, no treatment-related effects were noted at doses up to 20,000 ppm which corresponds to an average daily intake of 1068 mg/kg bw/day in males and 1284 mg/kg bw/day in females.

PMRA Response

With respect to the 2 year rat feeding study cited above, PMRA identified an error in the unit conversion from ppm to mg/kg bw/day. The correct NOEL values are 1068 mg/kg bw/day in males and 1284 mg/kg-bw/day in females. Following the revision of these values, the PMRA also determined that the chronic dietary exposure endpoint should be based on the no observed adverse effect level (NOAEL) of 900 mg/kg bw/day from the developmental toxicity study in rabbit, with support from the 2 year rat feeding study. Given the chronic dietary exposure to imazamox from food plus water for all subpopulations represented less than 10% of the acceptable daily intake (ADI) (based on the previous value of 8.7 mg/kg bw/day), the revised endpoint of 9.0 mg/kg bw/day does not significantly change the risk assessment outcome. Therefore, the proposed re-evaluation decision stated in PRVD 2015-04 remains unchanged. The revised endpoints are summarized in Table 1.

Table 1 Toxicology Endpoints for Use in Health Risk Assessment for Imazamox

Exposure Scenario	Dose (mg/kg bw/day)	Study	UF/SF or MOE[1]
Chronic Dietary	NOAEL[2] = 900	Developmental rabbit study, supported by 2 year rat oral (dietary) study; based on a slightly reduced mean maternal body weight gain during the dosing and post-dosing periods at the highest dose tested (900 mg/kg bw/day) and no effects observed up to and including the highest dose tested in rats (1068/1284 mg/kg bw/day ♂/♀)	100
	ADI[3] = 9.0 mg/kg bw/day, UF = 100		
Short- and intermediate-term dermal	NOEL[4] = 1000	28-day rat dermal study, no effects observed up to and including the highest dose tested (1000 mg/kg bw/day)	100
Short- and intermediate-term inhalation[5]	NOAEL= 900	Developmental toxicity study in the rabbit; based on a slightly reduced mean maternal body weight gain during the dosing and post-dosing periods at the highest dose tested (900 mg/kg bw/day)	100

1. UF/SF refers to total of uncertainty and/or safety factors for dietary assessments, MOE refers to target margin of exposure for occupational or residential assessments.
2. NOAEL refers to no observed adverse effect level.
3. ADI refers to acceptable daily intake
4. NOEL refers to no observed effect level.
5. An inhalation absorption factor of 100% (default value) is assumed for exposure assessment.

Appendix II Label Amendments for Products Containing Imazamox

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the label statements provided below.

I) Under **PRECAUTIONS**, the following statements must be added:

"Do not enter or allow workers entry into treated areas during the restricted-entry interval (REI) of 12 hours."

"Apply only when the potential for drift to areas of human habitation or areas of human activity such as houses, cottages, schools and recreational areas is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings."

II) The following statements must be included in a section entitled **ENVIRONMENTAL HAZARDS**.

"TOXIC to non-target terrestrial plants. Observe buffer zones specified under DIRECTIONS FOR USE."

"To reduce runoff from treated areas into aquatic habitats avoid application to areas with a moderate to steep slope, compacted soil, or clay."

"Avoid application when heavy rain is forecast."

"Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body."

"The use of this chemical may result in contamination of groundwater particularly in areas where soils are permeable (e.g. sandy soil) and/or the depth to the water table is shallow."

III) The following statements must be included in a section entitled **DIRECTIONS FOR USE**.

"**Field sprayer application: DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. Boom height must be 60 cm or less above the crop or ground."

"**DO NOT** apply by air."

"As this product is not registered for the control of pests in aquatic systems, DO NOT use to control aquatic pests"

"DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes"

Buffer Zones:

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands).

Method of Application	Crop	Buffer Zones (Metres) Required for the Protection of Terrestrial Habitat
Field sprayer	Alfalfa, bird's foot trefoil, *Brassica juncea*, canola, dry bean, field pea, lentil, soybeans, sunflower and wheat	1

For tank mixes, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture and apply using the coarsest spray (ASAE) category indicated on the labels for those tank mix partners."

The spray drift buffer zones for this product can be modified based on weather conditions and spray equipment configuration by accessing the Buffer Zone Calculator on the Pesticides and Pest Management portion of the Health Canada website.

Appendix III Registered Imazamox Products as of 8 March 2016

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
25109	Technical	BASF Canada Inc.	IMAZAMOX TECHNICAL HERBICIDE	Solid	IMZ: 97%
29027	Manufacturing Concentrate	BASF Canada Inc.	RAPTOR 1AS BULK	Solution	IMZ: 120 g/L
30506	Manufacturing Concentrate	BASF Canada Inc.	ARES BULK HERBICIDE	Solution	IMZ: 33 g/L ARS: 15 g/L
31422	Manufacturing Concentrate	BASF Canada Inc.	VIPER ADV BULK	Solution	BZN: 429 g a.e./L IMZ: 20 g/L
25110	Commercial	BASF Canada Inc.	AC 299,263 70 WDG	Water Dispersible Granules	IMZ: 70% a.e.
25111	Commercial	BASF Canada Inc.	ODYSSEY WDG HERBICIDE	Water Dispersible Granules	IMZ: 35% a.e. IMP: 35% a.e.
25496	Commercial	BASF Canada Inc.	SOLO WDG HERBICIDE	Wettable Granule	IMZ: 70% a.e.
26705	Commercial	BASF Canada Inc.	AC 299,263 120 AS HERBICIDE SOLUTION	Solution	IMZ: 120 g/L (present as ammonium salt)
27879	Commercial	BASF Canada Inc.	ADRENALIN SC HERBICIDE	Emulsifiable Concentrate	IMZ: 20 g/L DXF: 560 g a.e. /L
28741	Commercial	BASF Canada Inc.	SOLO WDG HERBICIDE (CLEARFIELD CROPS)	Water Dispersible Granules	IMZ: 70% a.e.
30188	Commercial	BASF Canada Inc.	ARES	Solution	IMZ: 33 g/L ARS: 15 g/L
30626	Commercial	BASF Canada Inc.	VIPER ADV	Solution	BZN: 429 g a.e./L IMZ: 20 g./L
31353	Commercial	BASF Canada Inc.	ODYSSEY ULTRA A (A COMPONENT OF ODYSSEY ULTRA HERBICIDE TANK MIX)	Water Dispersible Granules	IMZ: 35% a.e. IMP: 35% a.e.
31504	Commercial	BASF Canada Inc.	Salute B Herbicide	Solution	IMZ:15 g/L
32066	Commercial	BASF Canada Inc.	Solo Adv	Solution	IMZ: 25 g/L

IMZ – imazamox; ARS – imazapyr; IMP – imazethapyr; DXF – 2,4-D [(2,4-dichlorophenoxy)acetic acid]; BZN - bentazon